

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

N-Acetylcysteine (NAC) augmentation in the treatment of symptoms and cognitive function among patients with obsessive-compulsive disorder A double-blind placebo-controlled, randomized clinical trial

Protocol summary

Study aim

Comparison of treatment effect of N-Acetylcysteine (NAC) plus Sertraline with Placebo and Sertraline on OCD patients

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Settings and conduct

OCD outpatients who come to psychiatric clinics of Iran University of Medical Sciences will be recruited. Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. All of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Participants/Inclusion and exclusion criteria

Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 years old and sign consent form. they should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will evaluate for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Intervention groups

NAC plus Setraline and Placebo plus Sertraline
Main outcome variables
Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym

OCD

IRCT registration information

IRCT registration number: **IRCT20170123032145N7**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Mohammadreza Shalbafan

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1665

Email address

shalbafan.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

N-Acetylcysteine (NAC) augmentation in the treatment of symptoms and cognitive function among patients with obsessive-compulsive disorder A double-blind placebo-controlled, randomized clinical trial

Public title

NAC for treatment of Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 year old They should sign the consent form

Exclusion criteria:

They should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. Therefore, a table including 4: 1 blocks with random allocation of 2 numbers for each group will be given to a person other than recruiter/ evaluator and they will mark the medication box based on this numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore,

all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.IUMS.REC.1402.119

Health conditions studied**1****Description of health condition studied**

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes**1****Description**

Severity of obsessive-compulsive disorder

Timepoint

Weeks: 0, 4, 8 and 12

Method of measurement

Yale-Brown Obsessive Compulsive Scale(YBOCS)

Secondary outcomes

1

Description

Working Memory

Timepoint

Weeks: 0, 12

Method of measurement

Wisconsin Test

2

Description

Selective Attention

Timepoint

Weeks: 0, 12

Method of measurement

d2 Selective Attention Test

Intervention groups

1

Description

Intervention group: Sertraline(Tab) 200 mg/day plus NAC (Tab) 2400mg per day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Sertraline(Tab) 200 mg/day plus placebo(Tab) for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Tehran- Karaj Highway 7 km

City

Tehran

Province

Tehran

Postal code

1398913151

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Email

Shalbafan.mr@iums.ac.ir

Web page address

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2

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Reza Falak

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Grant name

High quality articles grant

Grant code / Reference number

1401-4-99-25244

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammadreza Shalbafan
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data about main outcome of study will be published

When the data will become available and for how long

2026

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For scientific goals

From where data/document is obtainable

shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

What processes are involved for a request to access data/document

Sending an E-mail and reason of request

Comments